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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,924	09/25/2000	Eric Raspe	MERCK 2157	2859
23599	7590	12/15/2004	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			CHUNDURU, SURYAPRABHA	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/646,924	<b>Applicant(s)</b> RASPE ET AL.	
	<b>Examiner</b> Suryaprabha Chunduru	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-12 and 14-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-12 and 14-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Applicants' response to the office action, filed on September 27, 2004 has been entered and considered.
2. Claims 1, 3-12, 14-30 are pending.

***Response to arguments***

3. Applicants' response to the office action are fully considered and found not persuasive.
4. The following is the rejection made in the previous office action under 35 USC 112, first paragraph:

Claims 1,3-12, 14-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to a method for screening a substance for usefulness in the treatment of lipid metabolism dysfunction which comprises a ROR $\alpha$  receptor or a response element of ROR $\alpha$  located at position -198 to +24, and a overlapping position -108 to +24. The claims recite the position of a response element of the apo C-III promoter involved in the regulation of the apo C-III gene. The specification does not support structural identity or sequence of the response element that specifically regulates the expression of apo C-III gene , It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, the response element of ROR $\alpha$  lacks such structural limitation and is not defined or described in the specification. The recitation of the position of a response element does not provide what structural limitation is responsible for the apo C-III gene expression. Further, the positions of a response element would comprise any sequence with any sequence variation by addition, deletion, substitution or insertion of one or more bases, which could result in substantially a different regulatory effect on the apoC-III gene.

Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that: "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the instant case, the lack of structural limitation of the said ROR $\alpha$  constitutes lack of written description.

***Response to arguments:***

With regard to the above rejection, Applicants' arguments have been fully considered and found not persuasive. Applicants argue that the promoter genomic elements described in the specification are well known to an ordinary skilled artisan at the time the application was filed and directs examiner's attention to the specific publications regarding apoC-III promoter and argues that the specification discloses how to obtain promoter fragments based on the known sequences. Applicants' further argue that according to MPEP 2163, nucleotide sequence

information is not necessary to establish possession of the invention. Applicants arguments are fully considered and found not persuasive because of the following reasons:

The independent claims recite a location of response element of ROR $\alpha$  in the apo C-III promoter region (position -198 to +24) without any start or end points, that is wherein the Apo CIII region these specific positions correspond to. Therefore promoter region recited in the instant claims lack support for the structural limitation (specific sequence identity), that is , where in the apo C-III promoter region does these positions correspond to. Where in the claimed promoter region the start (5'-end) and end (3'-end) positions are located and how the recited positions are numbered or organized in the claimed apo C-III promoter. The structural identity is necessary because, it is noted from the published literature that the apo C-III promoter elements are numbered differently. For example, in the published Genbank accession number X13367 (see the enclosed sequence numbering), it is noted that the sequence starts at 5'-end and numbering starts with position 1 and ends with 3'-end with position number 1381. With regard to the Reue et al. (J Biol. Chem., Vol. 263, pp. 6857-6864, 1988) disclosure the apo C-III gene 5' -flanking region starts with -812 and ends with -50 (see Fig.1). Thus the recited positions in the instant claims do not match with any of these sequence positions published and thus these recited specific positions lack a support for its structural limitations and do not have any support from the published literature. Further the overlapping positions -108/+24 of the apo C-III promoter location corresponding to the response element of ROR $\alpha$  in the location of -198 to+24 of the apo C-III promoter is not described.

Therefore, the rejection is maintained herein for claims 1, 3-12, 14-30.

#### ***Conclusion***

No claims are allowable.


**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Suryaprabha Chunduru  
December 1, 2004

  
JEFFREY FREDMAN  
PRIMARY EXAMINER  
12/5/04